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DIVISION OF METABOLISM AND ENDOCRINE DRUG PRODUCTS - HFD-510
Review of Chemistry, Manufacturing, and Controls

NDA #: 21-117

DATE REVIEWED: 12-20-99

REVIEW #: 1

REVIEWER: David B. Lewis

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	03-26-99	03-31-99	04-14-99
AMENDMENT	04-09-99		
AMENDMENT	07-30-99		
AMENDMENT	12-16-99		

NAME & ADDRESS OF APPLICANT:

Abbott Laboratories
Hospital Products Division
One Abbott Park Road
Abbott Park, Illinois 60064-3500

DRUG PRODUCT NAME

Proprietary:

10% Calcium Chloride Injection, USP in Plastic Syringe
(10 mL)

Established:

Code Name/#:

Chem. Type/Ther. Class:

3S

PHARMACOL. CATEGORY/INDICATION: calcium (chloride) injection/ for the treatment of hypocalcemia

DOSAGE FORM: Sterile solution of injection

STRENGTHS: 10% w/v in 10 mL solution

ROUTE OF ADMINISTRATION: Intravenous

Rx/OTC: ☒ Rx ☐ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Calcium chloride, USP dihydrate $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$

SUPPORTING DOCUMENTS:

Type/Number	Subject	Holder	Status	Review Date
DMF				

RELATED DOCUMENTS:

NDA 17-608	5% Dextrose & Lactated Ringer's Injection	Approved 8-13-75
NDA 17-635	Ringer's Irrigation in Semi-Rigid Containers	Approved 5-14-76
NDA 17-641	Lactated Ringer's Injection in Flex. Containers	Approved 1-07-76
NDA 18-251	Ringer's Injection in Flex. Containers	Approved 5-16-80
NDA 18-254	5% Dextrose & lactated Ringer's Injection	Approved 1-15-80
NDA 18-608	Cardioplegic Solution (Plegisol) in Flex. Containers	Approved 2-26-82
NDA 18-895	TPN Electrolytes in Plastic Vials	Approved 7-20-84

NDA 19-416 Lactated Ringer's Irrigation in Flex. Containers
NDA 19-685 Potassium Chloride in 5% Dextrose & Lactated Ringer's
Injection in PVC Flex. Containers

Approved 1-17-86
Approved 10-17-88

CONSULTS: Microbiology and Biopharmaceutics

PATENT INFORMATION: The drug product is not subject to patent and exclusivity per current edition of *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). (Section V, Vol. 6, p. 154) Patent certification and Exclusivity Statements are appended (Section VI, Vol. 6, pp. 155-156) per 21 § CFR 314.94(a)(12) and 314.94(a)(3).

DEBARMENT CERTIFICATION: The debarment certification for the application is attached (Section VIII, Vol. 6, pp. 164-166). *Abbott Laboratories ... certifies that it did not and will not use ... the services of any person debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.*

CONCLUSIONS & RECOMMENDATIONS: Adequate information has been supplied. The application is approvable, regarding chemistry, manufacturing and controls information.

CC:

Org. NDA 21-117
HFD-510/ Division File
HFD-820/Chemist/D Lewis/DGWu
HFD 510/S. McCort

APPEARS THIS WAY
ON ORIGINAL

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R/D Init by:

Filename: NDA 21-117 Review

/S/
David B. Lewis, Ph.D.
Review Chemist